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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,006	02/04/2000	Dr. Paddy Jim Baggot	249/127	9604

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/499,006	<b>Applicant(s)</b> BAGGOT, DR. PADDY JIM	
	<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-16 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***FINAL REJECTION***

1. This action is in response to the Amendment and Response filed October 27, 2004. Claims 15-16 and 21-23 have been amended, and claims 15-16 and 18-24 are now under consideration. Claims 1 and 17 remain withdrawn. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Election/Restriction***

3. Claims 1 and 17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

***Claim Rejections - 35 USC § 112***

4. In view of Applicant's arguments, and particularly Applicant's reference to the specific recitation of amniotic fluid at page 17, line 8 of the specification, the rejection of claims 15-16 and 18-24 under 35 U.S.C. 112, first paragraph is withdrawn.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS TO THE CLAIMS.**

5. Claims 15-16 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 15-16, 18-20 and 24 are indefinite over the recitation of the phrase "identifying....when a profile of metabolites in the amniotic fluid specimen differs from a control profile" in claim 15. It is noted that claim 15 previously requires steps of "compiling a profile of the amniotic fluid specimen" and "comparing the amniotic fluid specimen profile with a control profile." It is not clear from the language of the subsequent "identifying" step whether the recitations of a "profile of metabolites" and a "control profile" in that step refer back to the previously recited profiles, or whether any "profile of metabolites" and "control profile" may be employed in this step. Thus, it is not clear how the "identifying" step relates to the rest of the method steps of the claims. Further, it is not clear whether the language "profile...differs from a control profile" is intended to require, e.g., differences in quantities of metabolites (as is discussed previously in the claim), or whether (as the language of the claim literally suggests) any difference between any "profile of metabolites" and any "control profile" would be encompassed by the claims (such that, e.g., a "profile of metabolites" including metabolites A, B, and C would "differ" from a "control profile" including metabolites A, B, and D [and therefore meet the requirements of the claims] simply by virtue of including a different group of metabolites). Clarification is required.

Claims 16 and 18-19 are indefinite over the recitation of the limitation "the control profile" in each of the claims because claim 15, from which claim 16 depends, now recites multiple control profiles (one in the "comparing" step and one in the "identifying" step). It is not clear which of the control profiles of claim 15 would be considered to

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constitute "the control profile" (or whether this limitation might be applicable to both profiles). Clarification is required.

Claims 21-23 are indefinite over the recitation of the phrase "identifying the presence of Down Syndrome in the fetus from the identified plurality of abnormal quantities of metabolites" in claim 21. It is not clear whether this language indicates that the mere presence of a "plurality of abnormal quantities" is indicative of the presence of Down Syndrome, or whether this language indicates that the presence of Down Syndrome is to be ascertained in some manner using "the identified plurality of abnormal quantities." To the extent that further steps or further analysis of "the identified plurality of abnormal quantities" are/is required to identify the presence of Down Syndrome, further clarification is also required with respect to how the "identified plurality of abnormal quantities" may be used to arrive at an identification of Down Syndrome.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571/273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen  
Primary Examiner  
Art Unit 1634  
January 19, 2005